

## Michael Weingarten, Director, Small Business Innovation Research Program (SBIR) Office of the Director, National Cancer Institute



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The SBIR Program was established under the Small Business Innovation Development Act of 1982 and, by way of several reauthorizations, has since provided seed money for small companies involved in the development of innovative technologies. SBIR funding promotes a broad range of scientific activities and is available through such agencies as the Departments of Defense, Energy, and Health and Human Services (HHS). The

National Cancer Institute (NCI), part of HHS National Institutes of Health, confers SBIR grants and contracts (these are not loans) specific to the development and commercialization of oncology research.

As of May 2008, the NCI SBIR Program now includes a new pilot initiative referred to as the SBIR Bridge Award. This enhancement of the SBIR Program was highlighted in a scientific session at the annual meeting of the Biotechnology Industry Organization (BIO) June 17-20, San Diego, where the following interview was conducted.

**OBR:** *How did the new SBIR Bridge Award come about?*

**MW:** A little over a year and a half ago, Dr. Elias Zerhouni, Director of the National Institutes of Health (NIH), asked Dr. John Niederhuber, Director of the NCI, to propose some new ideas for how the overall SBIR program could be enhanced. So, Dr. Niederhuber formed a team made up of myself, Andy Kurtz, and John Hartinger, and what we did was survey the best practices for managing SBIR grants and contracts across a number of governmental programs including the National Science Foundation (NSF), NASA, and other agencies and came back with a set of recommendations, one of which was the Bridge Award.

**OBR:** *How has the program been administered to this point?*

**MW:** Companies apply first for a Phase 1 award, which is to test the feasibility of the concept being proposed. Typically, at the NIH, the average size of an award for a Phase 1 is about \$150,000. After a company has demonstrated the feasibility of the technology they apply for a Phase 2 follow-on award. That's a much

larger dollar size award at the NCI—on average, about a million dollars. It cuts across everything that the NCI does in terms of technologies that support cancer patients—everything from cancer treatments to diagnosis, prevention and cancer biology, from research tools to new drugs, to cancer imaging technologies, to biomarkers to diagnostics. At the NCI it's a \$100 million program.

**OBR:** *If a company receives both the initial and follow-on grants, that's a lot of money—why offer any more?*

**MW:** It is a lot of money but if we're talking about a drug or device development that needs to go through FDA approval you're still talking about the need for a lot more funds than that. I mean, what are the current projections—up to a billion dollars to get a drug approved?

**OBR:** *Why isn't the money coming from the Street?*

**MW:** Phase 1 and 2 dollars is really only enough to take a company maybe half the way through preclinical development. That leaves a lot of work remaining to get to the point where an IND is filed and a drug gets in to a clin-

ical trial. Unfortunately, after the SBIR money runs out, you might have promising data but haven't advanced the drug or technology far enough to where the private sector will step in and fully fund the ongoing development process. Typically, venture capital (VC) and other investors come in some time during Phase 1 or Phase 2 clinical trials, so we have this big funding gap we call "the valley of death"—that's where the project hasn't advanced far enough for the company to raise capital, yet, results looks promising. They just need a bit more cash to cross that valley. They need a bridge.

**OBR:** *Okay, so what exactly is this bridge made of?*

**MW:** We're going to provide a company up to \$3 million dollars in additional funds over a three year period but, in order to receive those funds a company is expected to go out and raise funds to match the NCI investment. That's what the National Science Foundation (NSF) found with their award, that the most successful aspect of it was this requirement for matching funds. So, yes, we're taking some of the risk away because we're going to come up with up to \$3

million, but a company needs to show that other parties are interested in their technology.

**OBR:** *Does a company get the money all at once?*

**MW:** The funds are released on a milestone basis. Program directors will be working with companies and managing projects very closely to make sure they're actually achieving the set of technical and commercial milestones that were proposed as part of the overall proposal. So, on an annual basis we'll be looking at technology milestones, the company's ability to stick to the proposed commercialization plan, as well as the company's ability to secure the matching funds for that year, and each year for the project to continue.

**OBR:** *Do the matching funds have to be cash?*

**MW:** It could be cash, obviously, it could be liquid assets. It could be stock that has value, for example, or it could be convertible debt. In early stage biotechnology companies, a lot are raising their funds right now as convertible debt. We've structured for a couple of different options.

**OBR:** *Is the program emphasizing certain technologies?*

**MW:** Two areas that we're focusing on right now are cancer therapies, and cancer imaging technology. Cancer therapies would cover small molecule drugs and biologics, and it would also cover radiation therapy. For cancer imaging technologies, we've found that this is one of the more productive parts of our portfolio in terms of the number of technologies that have reached can-

cer patients, so we think this additional award will really help companies in the imaging area get their technologies all the way to the point where they can be commercialized. New, effective cancer therapies and imaging technologies will ultimately help prevent, detect, and treat cancer.

**OBR:** *Sounds great – where does a company sign up?*

**MW:** Everything is on the Web site: <http://sbir.cancer.gov/>. There's a direct link to the solicitation, an overview of the program and how it's going to work, as well as all the other funding opportunities available from the NCI SBIR Program including tips on applying. We also have an e-mail alerts sign-up feature. For this first SBIR Bridge Award announcement we've got two receipt dates for companies to apply for the award: September 19, 2008 and February 27, 2009.

One of the things we've been doing a lot, which is why we come to venues like BIO, is we've been going out and doing workshops to educate people on how to apply for an award so that we receive quality applications. We want to increase the number and quality of applicants coming to us.

**OBR:** *Any advice on what not to do?*

**MW:** Don't propose an idea that's still more focused on the research rather than the translation and commercialization of technology. There are a lot of other mechanisms at the NIH that fund research but really, the purpose of this Bridge Award, and the ultimate success of the SBIR Program will be how many of these technologies we're able to move along the development pathway towards

commercialization. Beyond that, the main thing we want to see in the application is who a company expects its investors are going to be: They can be angel investors or VCs; universities or foundations; it can even be funds from the state. Many states are now offering matching SBIR funding programs.

**OBR:** *Can you give some examples of the sort of technology you've funded in the past?*

**MW:** GenVec is one. They have a drug in Phase 3 clinical trials right now which has received a number of SBIR awards that has helped develop it to the point where it's now at a very promising stage. Another important success story coming out of the program is a company called TomoTherapy. They developed an image-guided intensity-modulated radiation therapy for cancer treatment. Just a couple of years ago the company was still getting SBIR funding from us and now, they're up to \$230 million in sales with more than 700 employees. That's a great success story. We want to see all our companies get to that point. Ultimately, patients benefit from the therapies and technologies developed by successful SBIR awardees, with the help of small businesses and the NCI. **OBR**

For more information about the Bridge Award and other NCI Small Business Innovation Research & Small Business Technology Transfer (STTR) Programs funding opportunities, please visit <http://sbir.cancer.gov/> or call 301-594-7709.



We have all of our On-Conversations interview series available online, including those available through OBR daily and those you may have missed in print in previous issues of Oncology Business Review. Visit us online at [www.oncbiz.com](http://www.oncbiz.com).